On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

755. Adulteration and misbranding of Gilmore's Headache Powders. U. S. v. 45 Packages of Gilmore's Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 7354. Sample No. 86370–E.)

This product, in addition to being dangerous to health when used according to directions, failed to bear adequate directions for use and warning statements in the labeling, and contained acetanilid, caffeine citrate, and sodium bicarbonate greatly in excess of the amounts declared on the label.

On April 16, 1942, the United States attorney for the Northern District of Indiana filed a libel against 45 packages of the above-named article at Fort Wayne, Ind., alleging that it had been shipped in interstate commerce on or about November 11 and December 9, 1941, by the Don Gilmore Laboratories, Inc., from Cleveland, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate."

Analysis of a sample of the article showed that each powder contained 6.93 grains of acetanilid, 2.61 grains of caffeine citrate, and 2.50 grains of sodium bicarbonate.

It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess.

It was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Directions: Place a powder on the tongue and swallow with water. Repeat in twenty minutes if necessary," since when taken in accordance with these directions the powders would provide for the administration of slightly less than 14 grains of acetanilid in 20 minutes. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the powders contained acetanilid and the labeling contained no warning that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug; and, further, that the powders should not be given to children. (3) In that the label failed to bear adequate directions for use. (4) In that the statement on the label, "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate," was false and misleading.

On July 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[3]

756. Adulteration of triple distilled water and sterile solution of epinephrine chloride; misbranding of Suppletive Formula No. 1, Sterile Supportive Formula S. G. M. a., Sterile Solution Formula No. 1, Compressed Tablets No. 358, and Compressed Tablets Thyroid; adulteration and misbranding of Neohormestrin, solution of quinine and urea hydrochloride, quinine sulfate tablets, and sterile solution of ovarian extract. U. S. v. E. S. Miller Laboratories, Inc. Plea of nolo contendere. Fine, $75 on each of 4 counts. Imposition of sentence suspended on remaining counts and defendant placed on probation for 1 year. (F. D. C. No. 4132. Sample Nos. 7368–E, 7397–E, 7655–E, 7939–E, 30843–E, 31909–E, 31912–E, 32631–E, 53828–E to 53831–E. incl., 53833–E, 55734–E.)

This case involved the following violations and products: Failure to bear adequate directions, adequate warning statements, and satisfactory ingredient statements, Suppletive Formula No. 1 and Sterile Solution No. 1; failure to bear adequate directions and warnings, Compressed Tablets No. 358 and Compressed Tablets Thyroid; failure to bear adequate directions and ingredient statements, Sterile Supportive Formula S. G. M. a.; failure to comply with own standard of strength and quality and to bear satisfactory ingredient statement, Neohormestrin; failure to comply with official standard and reduction of quality because of the presence of minute particles of rubber, triple distilled water; failure to comply with official standards of strength and quality, quinine and urea hydrochloride, quinine sulfate, and epinephrine chloride.

[3] See also Nos. 754, 755.

On February 16, 1942, the United States attorney for the Southern District of California filed an information against E. S. Miller Laboratories, Inc., Los Angeles, Calif., alleging shipment within the period from on or about April 30, 1940, to on or about March 28, 1941, from the State of California into the States of Arizona, Illinois, and Oregon of quantities of the above-named drugs which were adulterated and/or misbranded.

The Suppletive Formula No. 1 was alleged to be misbranded in that its labeling failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since it contained emetine hydrochloride, and warnings that its use might cause vomiting, nausea, heart, kidney, stomach, or intestinal injury or disease unless administered in restricted dosage by a physician; and that it should not be administered over a continued period of time because of its cumulative toxic effects. It was alleged to be misbranded further in that its label did not bear the common or usual name of the drug contained therein, i. e., emetine hydrochloride.

The Sterile Solution Formula No. 1 was alleged to be misbranded in that its label failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration since it contained emetine and its labeling failed to bear warnings that its use might cause nausea, vomiting, heart, kidney, stomach, or intestinal diseases, that it should not be used in the presence of such pathological conditions; and that it might be especially dangerous for elderly persons and should not be administered to individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble except when administered by a physician. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

The Compressed Tablets No. 358 were alleged to be misbranded in that the labeling did not bear adequate directions for use since it bore no directions at all; and in that it failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since its labeling did not bear warnings that the tablets contained acetanilid frequent or continued use of which might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on said drug, and that it should not be given to children.

The Compressed Tablets Thyroid Substance were alleged to be misbranded in that the labeling did not bear adequate directions for use since it bore no directions at all; and in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where such use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since the article contained thyroid and the labeling failed to bear a warning that it might cause adverse effects on the body metabolism and the cardiovascular and central nervous systems, and that it should not be used by persons afflicted by heart disease or hyperthyroidism.

The Sterile Solution Neohormestrin was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since the labels of all 3 shipments represented that it possessed in each cubic centimeter a potency equivalent to that possessed by 2,500 International Units of oestrus-producing hormone and the label of one of the shipments represented that each cubic centimeter possessed a potency equivalent to that possessed by 500 Allen-Doisy rat units, namely, 500 rat units of oestrus-producing hormone; whereas it possessed a potency lower than that represented, tests of the three shipments having shown the following results: No. 1 was inert, No. 2 had a potency equivalent to that possessed by not more than 75 International Units of oestrus-producing hormone, and No. 3 had a potency equivalent to that possessed by not more than 55 International Units of oestrus-producing hormone equivalent to not more than 11 Allen-Doisy rat units. It was alleged to be misbranded in that the statements on the label, (2 shipments) "1 c. c. contains 2500 International Units Oestrus Producing Hormone," and (3d shipment) "Neohormestrin Each c. c. contains 2500 International * * * Units. 500 Rat (Allen-Doisey) Units," were false and misleading. One shipment was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of the active ingredient, i. e., oestrus-producing hormones.

The triple distilled water was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary but its strength differed from and its quality and purity fell below the standard set forth therein since when tested for oxidizable substances in accordance with the method prescribed in the formulary, it required more than 0.1 cc., namely, 1.6 cc. of twentieth-normal potassium permanganate to maintain a pink color; whereas the formulary provides that triple distilled water when tested in accordance with the method prescribed therein, shall require not more than 0.1 cc. of twentieth-normal potassium to maintain a pink color; and its difference in strength, quality, and purity from such standard was not plainly stated on the label. It was alleged to be adulterated further in that minute particles of rubber had been mixed or packed therewith so as to reduce its quality.

The Ampuls of Sterile Solution Quinine and Urea Hydrochloride were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the National Formulary, but their strength differed from and their quality fell below the standard set forth therein since each ampul yielded an amount of anhydrous quinine equivalent to less than 54.8 percent, namely, not more than 49.6 percent of the labeled amount of quinine and urea hydrochloride and 2 cc. of the article contained not more than 12.99 grains (0.838 gram) of quinine and urea hydrochloride; whereas the formulary specifies that unless another concentration of the solution is stated on the label, ampuls of quinine and urea hydrochloride shall contain a sterile solution of approximately 50 grams of quinine and urea hydrochloride in a sufficient quantity of ampul water to make 100 cc. (which is equivalent to 15½ grains (1 gram) of quinine and urea hydrochloride per 2 cc. ampul), and shall yield an amount of anhydrous quinine ($C_{20}H_{24}O_2N_2$) corresponding to not less than 54.8 percent of the labeled amount of quinine and urea hydrochloride; and its difference in strength and quality from such standard was not stated on the label. They were alleged to be misbranded in that the statement on the carton and ampul labels, "2 c. c. * * * Quinine and Urea Hydrochloride 15½ Grains (1.0 Gram)," was false and misleading.

The Sterile Supportive Formula S. G. M. a. was alleged to be misbranded (1) in that its label failed to bear adequate directions for use; and (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

The quinine sulfate tablets were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess in that they were represented to contain 5 grains of quinine sulfate; whereas each tablet contained not more than 2.09 grains of quinine sulfate. They were alleged to be misbranded in that the statement "Quinine Sulfate 5 Grs." was false and misleading.

One shipment of Solution Epinephrin Chloride was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its quality fell below the standard set forth therein since it contained in each 100 cc. of the solution not more than 0.05 gram of epinephrine; whereas the pharmacopoeia specifies that the article (which is recognized therein under the name "solution of epinephrine hydrochloride") shall consist of "a solution of epinephrine in distilled water and hydrochloric acid, containing in each 100 cc. not less than 0.095 Gm. * * * of $C_9H_{13}O_3N$," and its difference in strength and quality from the pharmacopoeial standard was not plainly stated on the label. The other shipment of Solution Epinephrin Chloride was alleged to be adulterated in that it purported to be and was recognized as a drug the name of which is recognized in the National Formulary but its strength differed from and its quality fell below the standard set forth therein since it contained in each cubic centimeter not more than 0.06 gram of epinephrine; whereas the National Formulary specifies that "Unless otherwise stated on the label, Ampuls of Epinephrine Hydrochloride contain measured quantities of sterile Solution of Epinephrine Hydrochloride (see U. S. Pharmacopoeia XI, page 207)," and the said pharmacopoeia specifies that "Solution of epinephrine hydrochloride is a solution of epinephrine in distilled water and hydrochloric acid, containing in each 100 cc., not less than 0.095 Gm. * * * of $C_9H_{13}O_3N$," and its difference in strength and quality from the standard set forth in the formulary was not plainly stated on the label.

The Solution of Ovarian Extract was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and

was represented to possess in that it was represented to contain in each cubic centimeter not less than 50 rat units of ovarian extract; whereas it contained in each cubic centimeter not more than 4 rat units of ovarian extract. It was alleged to be misbranded in that the statement on the label, "Ovarian Extract * * * 50 Rat Units per cc." was false and misleading.

On April 20, 1942, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of $75 on four of the counts, i. e., a total of $300; and ordered that imposition of sentence on the remaining counts be suspended for 1 year, that the defendant be placed on probation for 1 year, and that if no further violation occurred no further penalties be imposed.

757. Misbranding of Nomo For Piles, Sanafrio, and Asmolac. U. S. v. Albert B. Hirschman (Hirschman Laboratories and Sanafrio Laboratories). Plea of nolo contendere. Fine, $75 on each of 3 counts; sentence suspended on all but first count. (F. D. C. No. 5491. Sample Nos. 26467–E, 26469–E, 32632–E.)

The labeling of the Asmolac failed to bear adequate directions for use, such adequate warnings as are necessary for the protection of users, and a declaration of the alkaloids of atropine, hyoscine, and hyoscyamine that were present. The labeling of all three products bore false and misleading curative and therapeutic claims.

On November 3, 1941, the United States attorney for the Southern District of California filed an information against Albert B. Hirschman, trading as Hirschman Laboratories and as Sanafrio Laboratories, San Pedro, Calif., alleging shipment within the period from on or about May 14 to on or about July 1, 1940, from the State of California into the States of Arizona and Oregon of quantities of the above-named drugs which were misbranded.

Analyses of samples showed that the Asmolac consisted essentially of water, alcohol, plant extractives, alkaloids, reducing sugars, potassium iodide, and sodium iodide; that the Sanafrio consisted essentially of fat, zinc oxide, camphor, and menthol; and that the Nomo For Piles consisted essentially of benzocaine, boric acid, eucalyptus oil, fixed oils, and zinc oxide.

The Asmolac was alleged to be misbranded: (1) In that the directions for use contained no limitation as to duration of administration. (2) In that it contained (a) iodine or iodides and the labeling failed to warn that it should not be used in case of goiter except upon the advice of a physician and should be discontinued if skin rash appears; and (b) the alkaloids of belladonna and hyoscyamus and the labeling failed to warn that frequent or continued use should be avoided, that it should be used cautiously if dryness of the throat occurs, that it should be discontinued if rapid pulse or blurring of the vision occurs, and that it should not be taken by elderly people except upon competent advice. (3) In that the name "Asmolac" and the statements in the accompanying circular, "Where it is not deemed necessary to use Asmolac continuously, you should watch for the approaching of attacks such as nervousness, headache, itching of the nose or skin, severe sneezing, yawning, and other suggestive symptoms. If this is noticeable take half a teaspoon of Asmolac twice a day. In this way the actual spasms are usually to the greatest extent and often completely prevented," were false and misleading since they represented that when used as directed in the above-named conditions, it often would completely prevent the actual spasms of asthma; whereas if used as directed, it would not often, nor at all, completely prevent the actual spasms of asthma. (4) In that it contained the alkaloids of atropine, hyoscine, and hyoscyamine, but the labeling did not contain the name and quantity or proportion of said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids of belladonna and hyoscyamus that it contained.

The Nomo For Piles was alleged to be misbranded: (1) In that the name "Nomo For Piles" and the statements in the labeling, (carton only) "Astringent," (carton, tube, and circular) "To Relieve * * * Soreness * * * Associated with Piles," and (circular) "For the relief of pain it is highly recommended," were false and misleading since they represented and suggested that it was a competent treatment for all cases of piles and would be efficacious to relieve the soreness and pain associated with piles; whereas it would not accomplish such results. (2) In that the labeling was misleading since it failed to reveal the fact, material in the light of the representations which it contained, that the preparation did not constitute a treatment for all kinds of piles and that competent advice should be secured in cases of excessive bleeding.